

ATTACHMENT 1

**PETITIONS FOR RULEMAKING
(PRM 50-63 AND PRM 50-63A)**

4809 Drummond Avenue
Chevy Chase, MD 20815
September 9, 1995

Mr. John C. Hoyle, Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Petition of Peter G. Crane for rulemaking to
implement the recommendation of the President's
Commission on the Accident at Three Mile Island (Kemeny
Commission) that the United States stockpile the drug
potassium iodide for thyroid protection during nuclear
accidents

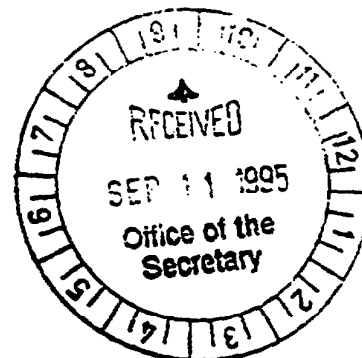
Dear Mr. Hoyle:

Enclosed for filing please find the above-captioned petition. Please note that it is submitted in my capacity as a member of the public, not in my official capacity as Counsel for Special Projects in the NRC's Office of the General Counsel. It was written on my own time, at home, using information available to the public in the NRC's Public Document Room.

Sincerely,

Peter G. Crane

Peter G. Crane



BEFORE THE UNITED STATES NUCLEAR REGULATORY COMMISSION

Petition of Peter G. Crane for rulemaking to implement the recommendation of the President's Commission on the Accident at Three Mile Island (Kemeny Commission) that the United States stockpile the drug potassium iodide for thyroid protection during nuclear accidents

I. Summary

The subject of this petition should be of nationwide concern: the fact that the United States, unlike virtually all other countries in the developed world, does not stockpile the drug potassium iodide (KI) to prevent thyroid cancer and other thyroid diseases after nuclear accidents. KI prevents the absorption of harmful radioactive iodine by saturating the thyroid gland with iodine in a harmless form. The drug is extremely inexpensive. In recommending stockpiling in 1994, the NRC technical staff estimated that a supply sufficient to protect the population nearest to all U.S. nuclear plants could be established for a total of at most "a few hundred thousand dollars," or ten cents per year for each person protected.

Present U.S. policy, adopted in 1985 by an interagency policy statement, with NRC concurrence, holds that it is "not worthwhile" to require KI stockpiling. The policy reflects a "cost-benefit analysis" which calculated that the drug was not likely to pay for itself over time, and that it would be cheaper in the long run to refrain from buying KI, and treat the resulting thyroid disease, than use KI to prevent the disease. Looking only at dollar costs, the analysis did not take into account what we all know intuitively: that the worst part of illness is not necessarily the economic consequences.

Currently, the federal government is sending confused and confusing messages both about whether KI is useful and whether it is available. In September, 1994, the Federal Emergency Management Agency issued a proposed Federal Radiological Emergency Response Plan describing the duties of federal agencies during nuclear emergencies. The NRC, as the lead agency for accidents at nuclear power plants, is to advise state and local governments about "measures that they should take to avoid or reduce exposure of the public to radiation," including "emergency actions such as sheltering, evacuation, and prophylactic use of iodine." In an emergency, an interagency panel will offer guidance to the NRC on when KI should be used. While the authors of the Plan plainly understand the drug's value in radiological emergencies, they seem not to realize that because of the 1985 policy, all the elaborate procedures for making decisions about

KI are pointless: in an emergency, there will be none to give out.

The 1985 policy statement was the complete rejection of one of the major recommendations of the President's Commission on the Accident at Three Mile Island (Kemeny Commission). During the TMI accident, state and federal officials looked for KI and discovered that none was available. The drug had to be manufactured on short notice. The Kemeny Commission strongly criticized the failure to stockpile, and recommended that regional stockpiles be established. Its report recognized that evacuation is not invariably the preferred response to an emergency, and that even when evacuation is desirable, it may not be feasible. A KI stockpile means that emergency response officials have three arrows in their quiver: evacuation, sheltering, and iodine.

Initially, in 1979, the NRC warmly endorsed the Kemeny Commission's position on KI and announced that it intended to make the availability of KI for the general public a necessary part of every emergency response plan. As late as September 1982, all the responsible federal agencies were in agreement that KI stockpiling was desirable. A draft federal policy statement to that effect was circulated for agency approval. Only a few weeks later, for reasons still unclear, FEMA and the NRC staff did a complete about face. FEMA cancelled its plans to purchase KI, the draft policy statement was withdrawn, and the NRC staff adopted a strongly negative stance toward KI.

The NRC Commissioners' acceptance of the NRC staff's changed position came after a November 1983 briefing in which staff officials, none of whom is now with NRC, offered a seriously inaccurate description of the nature of the disease that KI could be expected to prevent. Never discussing cancers or fatalities, the briefers advised the Commissioners and the audience that if a member of the public was exposed to radioactive iodine during an accident, the result could be a "nodule," easily removed, that would mean "a few days" of absence from work. The briefers did not mention that 40% of those radiation-caused nodules would be cancerous, and that 5 to 10% of the cancers would be fatal.

The actual consequences of radiation-caused thyroid disease are far more serious than "a few days" away from work, as the recent news reports on the young victims of Chernobyl make grimly clear. Though usually curable, thyroid cancer is lethal enough to kill 1,120 Americans each year, according to American Cancer Society figures. Even when non-fatal, the disease and related tests and treatment can severely affect the quality of life.

In 1986, only a year after the policy statement was issued, the Chernobyl accident demonstrated how dangerously flawed the new U.S. policy was. In Poland, where the authorities moved vigorously to administer KI, 18 million doses were given out, with the result that 97% of all Polish children were protected and an upsurge of disease was averted. In the then Soviet Union, on the other hand, too little KI was given out, too late. Russia, Belarus, and Ukraine are now experiencing soaring rates of childhood thyroid cancer -- in some places, 200 times pre-accident levels -- and the worst may be yet to come.

U.S. policy did not change in response to the Chernobyl accident, however, despite an urgent request from the American Thyroid Association in 1989. In 1991, the World Health Organization declared that thyroid protection was "critical" during accidents, and said, "Stocks of iodine should be stored strategically at points including hospitals, schools, and fire and police stations." France, Germany, Belarus, Russia, Switzerland, Austria, the Czech Republic, Japan, Britain, Sweden, Slovakia, and a host of other countries now protect their children with stockpiles of KI. They follow the "International Basic Safety Standards," issued by the International Atomic Energy Agency in 1994, which provide for giving out KI when projected doses exceed specified guidelines. The U.S. Government supported adoption of the Basic Safety Standards, which represent the consensus judgment of the world's radiation safety experts, but ignores them where KI is concerned.

The current policy goes against the best judgment of the NRC's own technical staff, which in 1994 declared, commendably, that "prudence" called for KI stockpiling and recommended to the NRC Commissioners that the U.S. Government buy the drug and make it available to states at no cost. While the NRC staff's proposal for a change in policy was pending before the Commissioners, Senators Alan K. Simpson and Joseph I. Lieberman, in an April 20, 1994 letter, urged the Commission to bring American policy on KI into line with the recommendations of medical and scientific experts and international practice. They also stressed the "moral responsibility" of the federal government to be candid with the public about the risks of federally-licensed activities and ways of lessening those risks.

The only group to endorse the existing policy was an industry trade association, which urged among other things that stockpiling KI might make the public fear that nuclear plants were unsafe. And so the lines were drawn: on the one side, the Kemeny Commission, the American Thyroid Association, the World Health Organization, the two Senators, the NRC's own technical

staff, and the example of the rest of the developed world; on the other side, the industry trade association. When the Commissioners cast their votes, the outcome was a 2-2 tie. Under NRC procedures, the deadlock meant that the NRC staff proposal failed. The old discredited policy remains in place today.

FEMA's 1994 Federal Radiological Emergency Response Plan takes the worst of all possible approaches, for it gives states and the public the illusion of KI protection without the reality. The Government must choose: either to create stockpiles of KI, thereby making the Plan accurate, or revise the Plan and publicly explain that because of the existing federal policy, use of the drug will not be an option in a nuclear emergency.

This petition would resolve the dilemma by improving protection rather than correcting the Plan. It requests that the Commission amend its rules (10 CFR Section 50.47(b)(10)) to specify that the "range of protective actions" required to be set forth in State and local emergency plans includes sheltering, evacuation, and provision to administer KI, as envisioned by the Federal Radiological Emergency Response Plan. It asks the NRC to issue a policy statement explaining that KI is a sensible and prudent emergency planning measure, when used in conjunction with evacuation and sheltering, and declaring NRC support for federal funding of local and regional stockpiles. This approach would cost utilities nothing, and should not burden them in any way. For a pittance, it could save thousands of Americans from thyroid cancer and other diseases if a major nuclear accident occurred.

KI may be compared to the lifejackets on a ferryboat: needed only rarely, but vital if the need does arise. We require ferries to carry lifejackets not because we expect them to pay for themselves over time, but because it is the reasonable and prudent thing to do. Likewise, we vaccinate our children against polio and diphtheria to prevent needless suffering and deaths, not because we have calculated that this is a way to save money.

The U.S. Government recently agreed to spend \$15 million over 15 years studying radiation-related thyroid cancer in Ukrainian children. This was sensible and appropriate. But can a rational Government decide that it is worthwhile to spend \$15 million to study thyroid cancer in Ukrainian children, and not worthwhile to spend a fraction of that amount to prevent the same disease in American children? This petition says that it can't. America's families deserve no less protection from radiation than is provided to children and their parents throughout the rest of the developed world. The NRC staff has pointed the way, and the Commission and the U.S. Government should follow.

II. Factual Background

A. Potassium iodide and its uses.

Potassium iodide (KI) protects the thyroid gland -- which, especially in children, is highly sensitive to radiation -- from the radioactive iodine that would be released in extremely serious nuclear accidents. By saturating the gland with iodine in a harmless form, potassium iodide prevents any inhaled or ingested radioactive iodine from lodging in the thyroid gland, where it could lead to thyroid cancer or other illnesses.

In addition to preventing deaths from thyroid cancer,¹ KI prevents radiation-caused illnesses that although not fatal, can disrupt and even blight a person's life. Thyroid cancer, curable in 90-95% of cases, generally means surgery, radiation treatment, and a lifetime on medication.² The changes of medication that go with periodic scans put many patients on a physiological and

¹ The American Cancer Society estimates the number of new cases in 1995 at 13,900, and the number of deaths at 1,120. Thyroid cancer represents about 1 percent of cancer cases nationwide.

² See letter of Joseph E. Rall, M.D., Ph.D., Deputy Director for Intramural Research, National Institutes of Health, to Central Docket Section, Environmental Protection Agency, February 9, 1990:

In the United States, there are approximately 10,000 new cases of thyroid cancer per year. After initial surgical removal, ablation with I-131 is used to complete the thyroidectomy in in at least half of these patients (i.e. ~5000) in doses ranging from 30 to 150 mCi. Most of these patients then receive one or more test doses of I-131 (2 to 10 mCi) to detect the occurrence of metastases. A conservative estimate of the number of patients who develop metastatic thyroid cancer who could benefit from I-131 therapy is 2000 cases per year. These patients receive from one to ten treatment doses of 150 to 300 mCi over a period of up to 20 years or more. This treatment is curative in some cases and prolongs disease-free survival in many cases.

It should also be noted that unlike some cancers, which if they have not recurred within a set period (such as five years) can be considered cured forever, the thyroid cancer patient must be monitored for life.

psychological rollercoaster.³ Hypothyroidism (an insufficiency of thyroid hormone, which can result from radiation damage to the gland) can cause permanent retardation in children and, if undiagnosed, can condemn adults to a lifetime of fatigue, weakness, and chills.⁴ The drug has a long shelf life -- at least five years -- and causes negligible side effects.⁵

B. U.S. policy on KI prior to the Three Mile Island accident.

In December 1978, the Food and Drug Administration announced that it had determined that potassium iodide was safe and effective for thyroid protection in nuclear accidents. The issue attracted little attention, however, and the NRC and the Federal Government as a whole took no public position on the drug.

Barely three months later, on March 28, 1979, the Three Mile Island accident began to unfold. After two days of unsuccessful efforts to bring the reactor under control, it was still uncertain whether a major release of radioactivity could be averted. Federal and state officials, searching for supplies of KI in case it should be needed, discovered that there was none to be had, in Pennsylvania or elsewhere. A supply therefore had to

³ Some years ago, for example, Senator John East of North Carolina committed suicide because, according to his widow, an incorrectly treated thyroid imbalance had made his life unendurable. President George Bush, after being treated with radioactive iodine for an overactive thyroid (Graves' disease), displayed symptoms characteristic of patients returning to thyroid hormone after the hypothyroidism caused by radioiodine treatments: physical exhaustion, frequent talkativeness, and a tendency to emotionalism. The media may have missed the story (as President Bush's former press secretary observed in recently published memoirs), but at the time, old thyroid patients understood exactly what was going on.

⁴ As I had occasion to see when I was in the Marshall Islands as an administrative judge with the Nuclear Claims Tribunal in 1991, many people who are chronically chilly and exhausted from hypothyroidism may be unaware that their problems are symptoms of a treatable illness. As a result, they may never receive the drug (synthetic thyroid hormone) that would quickly relieve their symptoms and allow them to live a normal life.

⁵ "Iodide Prophylaxis in Poland after the Chernobyl Reactor Accident: Benefits and Risks," Janusz Nauman, M.D., Ph.D., Jan Wolff, M.D., Ph.D., The American Journal of Medicine, Vol. 94, p. 524 (May, 1993).

be manufactured, literally overnight. At 3 a.m. on Saturday, March 31, a Food and Drug Administration official arranged with the Mallinckrodt Chemical Company for the immediate production of 250,000 doses of KI. Without a written contract or a purchase order, the company began production (Parke-Davis soon followed suit), and the first shipment of the drug arrived in Pennsylvania 24 hours later.⁶

C. The President's Commission on the Three Mile Island accident recommends KI stockpiling.

After the accident, President Carter appointed John Kemeny, President of Dartmouth College, to head a commission to investigate the accident. Its report, issued in October, 1979, was strongly critical of the failure to stockpile KI. It said:

For over 25 years, the use of blocking agents such as potassium iodide to prevent the accumulation of radioiodine in the thyroid gland has been known. The effectiveness of potassium iodide administration for thyroid gland protection in the event of releases of radioiodine was recognized by the National Council on Radiation Protection and Measurement in 1977. The Food and Drug Administration authorized use of potassium iodide as a thyroid-blocking agent for the general public in December 1978. However, at the time of the TMI accident, potassium iodide for this use was not commercially available in the United States in quantities sufficient for the population within a 20-mile radius of TMI.⁷

Among the Kemeny Commission's major recommendations was the following:

⁶ "Report of the Office of Chief Counsel on Emergency Response to the President's Commission on the Accident at Three Mile Island," (October 1979), p. 91. See also Dr. Jerome Halperin, "Potassium Iodide as a Thyroid Blocker -- Three Mile Island to Today," DICP, The Annals of Pharmacotherapy, Vol. 23 (May 1989), which includes an insider's account of the effort to procure not only supplies of the drug, but also bottles, labels, and droppers, and get them to Pennsylvania.

⁷ Report of the President's Commission on the Accident at Three Mile Island, October 1979, at 41-42. With a single change - from 25 years to 40 -- this would be also be an accurate statement of current preparedness to administer KI.

An adequate supply of the radiation protective (thyroid blocking) agent, potassium iodide for human use, should be available regionally for distribution to the general population and workers affected by a radiological emergency.'

Elsewhere in its report, the Kemeny Commission explained that different types of accidents, depending on their particular circumstances, might require different kinds of emergency response:

A variety of possible accidents should be considered during siting, particularly "smaller" accidents which have a higher probability of occurring. For each such accident, one should calculate probable levels of radiation releases at a variety of distances to decide the kinds of protective action that are necessary and feasible. Such protective actions may range from evacuation of an area near the plant, to the distribution of potassium iodide to protect the thyroid gland from radioactive iodine, to a simple instruction to people several miles from the plant to stay indoors for a specified period of time. ... Emergency plans must have built into them a variety of responses to a variety of possible kinds of accidents.'

The last point is particularly significant, because it shows the Kemeny Commission's recognition that in some accident situations, evacuation may not be the emergency planning measure of choice.

D. The federal agencies back the Kemeny Commission recommendation.

Initially, the Kemeny Commission's recommendation in favor of KI stockpiling seemed so obviously sensible as to be non-controversial. In NUREG-0632, "NRC Views and Analysis of the Recommendations of the President's Commission on the Accident at Three Mile Island," issued in November, 1979, the NRC declared:

The President's Commission recommends that an adequate supply of potassium iodide be available for both workers and the general public. NRC agrees and is

⁸ Id. at 75.

⁹ Id. at 16-17.

planning to require licensees to have adequate supplies of this agent available for nuclear power plant workers. For the general population, NRC expects to include the availability of potassium iodide as a necessary part of an acceptable State emergency response plan. Plans have not been finalized as to exactly how and to what extent the agent should be stockpiled and distributed, but studies are underway to resolve this matter at an early date.

For the next several years, the three agencies most concerned -- the Food and Drug Administration, responsible for approving drugs; NRC, expert in radiation protection; and the Federal Emergency Management Agency, with responsibilities for emergencies generally -- were all on the same track, favoring the stockpiling of potassium iodide. In May 1982, however, the Atomic Industrial Forum, a nuclear industry trade association, declared itself against potassium iodide.¹⁰

The NRC staff was strongly in favor of KI stockpiling as late as September 27, 1982, when it sent the Commissioners a memorandum numbered SECY-82-396 ("Development of a Federal Policy Statement on the Distribution and Use of Potassium Iodide for Thyroidal Blocking in the Event of a Nuclear Power Plant Accident"). In that paper, the staff proposed that the Commission agree with a draft interagency policy statement supporting KI stockpiling.

The draft policy statement is worth quoting at length, because it describes with clarity and accuracy both the benefits of KI and the limitations of the drug. It says:

....KI blocking only effectively reduces the radiation exposure of the thyroid gland. While this is an important contribution to the health and safety of the individual, it is not nearly as effective as measures which protect the total body of the individual from radioactivity. Both in-place sheltering and precautionary evacuations can reduce the exposure to the total body. As an example, if a precautionary evacuation can be instituted with little or no radiation exposure, this may be the most effective

¹⁰ "Statement on the Use of Potassium Iodide by the Atomic Industrial Forum Committee on Environment," cited in the "Industry White Paper, Review of Federal Policy on Use of Potassium Iodide," December 1993, at 7.

protective action. However, there are instances where evacuation may not be preferred. Evacuation may be unnecessary because the amount of protection afforded by in-place sheltering is adequate....There are also possible situations when evacuation cannot be accomplished in time to prevent exposing large numbers of individuals to a significant amount of radiation during the evacuation. In those instances where shelter is used because the evacuation cannot be completed in time to avoid a substantial radiation insult, the administration of KI could be a useful ancillary protective action which could provide some additional exposure reduction to the thyroids of the exposed individuals. The use of KI for thyroidal blocking is not an effective means by itself for protecting individuals from an airborne release of radioactivity from a nuclear power plant accident and therefore should be used in conjunction with sheltering, evacuation or other protective methods. ... In summary, the use of KI to prevent radioiodine from accumulating in the thyroid gland can be an effective ancillary protective action during a nuclear power plant accident.¹¹

E. The NRC and FEMA reverse themselves.

For reasons that have never been explained publicly, the policy statement was almost immediately scuttled. Less than three weeks after sending the draft policy statement to the Commission for approval, the staff sent a supplementary paper, SECY-82-396A (October 15, 1982), withdrawing the September 27 memorandum. The new memo informed the Commissioners that NRC's Office of Research could, by January 1, 1983, produce a paper showing that KI was "significantly less cost beneficial than previously assumed." The staff proposed sending this document, when completed, to the other federal agencies "with a recommendation that a policy statement recommending against the stockpiling and distribution of potassium iodide for the general public be developed." The staff paper added a significant piece of information: "The Commission should also be aware that FEMA has recently reversed its previous decision to purchase a large quantity of potassium iodide for a national stockpile." The reason for FEMA's action was not stated, however.

In a November 22, 1983 Commission meeting, open to the

¹¹ SECY-82-396 (September 27, 1982), Attachment 3, at 3-4.

public, Jack Zerbe, head of the NRC's Office of Policy Evaluation, expressed his unease at the NRC staff's sudden about-face:

I guess one of the things that was of concern to us was that in 9/27/82, the staff had recommended that they adopt this thing that had been worked on for four years by the three agencies, and essentially two weeks later they shifted that recommendation to go in just the opposite direction.

Transcript at 79.

The implied question -- why the reversal had occurred -- went unanswered. No claim was made, then or later, that the change was based on new scientific, technical, or medical information.

The purpose of the November 22, 1983 meeting was for the NRC staff to brief the Commissioners on the staff's proposal to take a strong position against KI. At the outset, the three staff briefers¹² emphasized that the NRC had the primary role within the U.S. Government as a source of technical expertise on the KI issue.¹³ One of the briefers explained:

We, at the NRC, have the responsibility to provide the technical rationale and make some recommendation either for potassium iodide, a neutral statement one way or another, or against it. And that's where we have to come down, in some sense. It is our responsibility to provide that technical information.

Transcript at 7.

A problem for the briefers, in making the case against KI, was that the Commissioners had been hearing ever since the Three Mile Island accident that stockpiling the drug was a cheap, effective, and sensible protective measure. As Commissioner Bernthal commented at one point, "I just think stockpiling is such a cheap and easy preventative, that even if the odds are 1 percent, why not?" (Transcript at 28.) The briefers undertook to prove that even though KI might cost only ten cents per pill, it was nevertheless not "cost-effective."

¹² None of the three is still with the NRC.

¹³ This was correct then and remains so today.

The briefers' central claim was that it would take \$10,000,000 worth of KI to prevent each "nodule,"¹⁴ whereas if KI were not used, the cost of dealing with each nodule that did occur would be at most \$20,000. The transcript is clear on this point:

At the bottom of this [slide], you see a dashed line at about the \$20,000 figure, and that represents what we feel the cost-benefit breakpoint would be. If the cost of averting one nodule is on the order of \$20,000, that's the cost that will be represented by the medical treatment and the loss of productivity of an individual if he had a thyroid nodule. And it's on the upper end of the values which we have seen. There's a few days' loss from -- it's a relatively simple operation that's involved in removing the thyroid or removing the nodules¹⁵ -- [Emphasis added.]

Transcript at 52-53.

The briefers claimed to have performed the analysis "with a bias in favor of potassium iodide if anything." (Transcript at 53.) They continued:

And our analysis still comes down and shows that even if our most optimistic view -- which is the bottom line of these curves -- would indicate that this is not a viable measure to be taken, it is not something that we should consider in terms of policy. As far as we're concerned, the message couldn't be any clearer. ... We have taken every factor that we can think of into account; it's not just single arguments that we throw at each other; we have factored in all the uncertainties that we can think about, and this is where we come down to it, and the message is clear.

Transcript at 54.

The transcript shows the Commissioners' response:

¹⁴ The \$10,000,000 figure reflected the assumption that an accident in which KI would be useful could occur only once a millenium.

¹⁵ Compare this description of thyroid disease with that quoted in footnote 2, above.

CHAIRMAN PALLADINO: But it sounds crass. It doesn't satisfy me as an individual.

COMMISSIONER ASSELSTINE: I must say I share that view.

CHAIRMAN PALLADINO: Something just does not sit with me right.

[Staff briefer]: Let's move on to the next slide.

(Laughter.)

Transcript at 54.

The Commissioners' misgivings were well-founded. While the briefers' clear and unequivocal message was that the worst consequence of failing to stockpile KI was that a "nodule" might appear, they neglected to mention that their figures were based not on all nodules, but only on harmless benign ones. Their own analysis showed that some 40% of all accident-caused nodules will turn out to be cancerous, and that 5% to 10% of the cancers will be fatal.¹⁶

Chairman Palladino persisted. Told that the NRC should provide its cost-benefit analysis to other federal agencies and state and local governments "because these other agencies do look to the Nuclear Regulatory Commission," (Transcript at 57), he replied:

I'm not ready yet to even address that because I don't understand in the cost analysis -- for example, you say it costs -- what were your dollars? \$10 million per nodule averted, and you said boy, that's pretty high. But then you tell me it's a low cost operation. So now to me, for example, as an individual, what would it cost me for my pill. Twenty cents. ... As an individual, I say boy, that's among the lowest-cost protection. ...

... I guess I was taking a more personal view of cost-benefit. 20 cents or some nominal amount of money every year or every five years to replace them seems

¹⁶ This fact was buried in the fine print of the thick memorandum that accompanied the briefing. The transcript suggests that the Commissioners had not picked up on this critical point.

like small change compared to the risk, from my perception.

Transcript at 57, 59, 60-61.

One of the staff briefers responded by comparing potassium iodide to insurance policies with low premiums but with coverage that turns out, on close examination, to require "that there has to be a stampeding elephant that kills you." (Transcript at 61.)

CHAIRMAN PALLADINO: ...You said something that bothers me a little bit. You said that we were paying a low cost for something that wasn't worthwhile. You related it to a worthless insurance policy. But as an individual, I may say the potential benefit is that I might survive a nuclear accident at that plant, which I live near.

COMMISSIONER ASSELSTINE: Or that you may not have to go through an operation --

[Staff briefer]: Except that -- the surviving question is not the question, and that's the piece that really should also be emphasized.¹⁷ [Emphasis added.]

CHAIRMAN PALLADINO: All right, survive in the terms of I avert --

[Another staff briefer]: An illness. I will avert an illness which I might incur. But my father's argument in buying his insurance policies was the very same. He might leave my mother \$10,000 from an accident insurance policy. There was a residual chance that he would be killed by that stampeding elephant. It was not a well thought-out choice.

¹⁷ The clear implication of this statement was that potassium iodide cannot save lives. The staff briefer treated Chairman Palladino's comment as referring only to immediate, short-term survival. To be sure, potassium iodide will not prevent quick deaths during an accident (if people die from radiation in the short term, it will be because of whole-body doses, not thyroid doses), but it may prevent slow deaths from cancer in the years afterwards. For the three or four Americans who die of thyroid cancer each day, and all the thyroid cancer patients who, being human, worry that the disease may kill them, "the surviving question" is thus very much the question.

Transcript at 63.

Continuing the theme that the drug was a useless remedy against a non-existent problem, one of the staff briefers added that the staff did not feel it necessary to come out in opposition to the purchase of KI by individuals: "If somebody wants to wear that amulet and have that available to them, that's their business...." (Transcript at 68.)

The issue was not finally resolved that day, but in the end, the NRC's negative views on the drug were communicated to an interagency group studying the issue.¹⁸ The result was the 1985 Policy Statement, still in effect today, which declared:

While valid arguments may be made for the use of KI, the preponderance of information indicates that a nationwide requirement for the predistribution or stockpiling for use by the general public would not be worthwhile. This is based on the ability to evacuate the general population and the cost effectiveness of a nationwide program which has been analyzed by the NRC....¹⁹

The net effect of the Policy Statement was to dispose of the Kemeny Commission's recommendation in favor of KI stockpiling,

¹⁸ I do not mean to suggest that the Commissioners remained under the impression that thyroid cancer was never fatal. As I described in my Differing Professional Opinion, the Office of General Counsel pointed out to the Commission that the staff's figure of \$20,000 referred only to the costs associated with having a harmless benign thyroid nodule. In reply, the staff acknowledged that if both benign and malignant nodules were taken into account, the costs would go up by a factor of five, to \$100,000. No public announcement of this was made, however, so the recalculation would have been of no benefit to those members of the public who attended the November 22 briefing at which the \$20,000 figure was touted.

¹⁹ "Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent," 50 Fed. Reg. 30258 (July 24, 1985). Note that the Policy Statement does not say that KI itself is not worthwhile; it is the requirement to stockpile or predistribute the drug that is described as not worthwhile. But the ordinary reader will not notice this artful distinction, and will understand the Government to say that the drug itself is worthless. Note also the implication that it will always be possible to evacuate the affected population if an accident occurs.

seemingly once and for all. What could not have been predicted, however, was that only a year later, a nuclear catastrophe in the Soviet Union would give tangible proof of the value of the drug in radiological emergencies.

F. Chernobyl and its aftermath

During the Chernobyl accident of 1986, the damaged reactor spewed radioactive iodine not only into the immediate vicinity of the plant (located near Kiev in Ukraine), but also over wide areas of the Soviet Union and nearby Poland. Russia, Ukraine, and Belarus, where the distribution of KI was inadequate and untimely, are now experiencing extraordinarily high levels of childhood thyroid cancer, as recent newspaper articles have described.²⁰ The reports from Eastern Europe make clear that

²⁰ "Chernobyl's Young Victims Pay Toll: Thyroid, Other Cancers Are Belarus's Legacy of Nuclear Disaster," a front page article in The Washington Post, June 24, 1995: "In 1986, before Chernobyl, according to Yevgeny Demidchuk, director of the republic's Scientific and Practical Center of Thyroid Cancer in Minsk, Belarus registered just two cases of thyroid cancer in children under 14, about a typical number for a country its size. By 1992 that number had soared to 66 cases and last year to 82, a surge so sudden and severe that international experts, initially skeptical about Belarus's post-Chernobyl health claims, now acknowledge it can only be explained by Chernobyl fallout. ... Pre-cancerous thyroid conditions in children are even more widespread. 'This is on a mass scale, several million kids who might develop thyroid cancer,' said Konoplya [director of the Radiobiology Institute of Belarus's Academy of Sciences]."

See also, "Cancers Soar in Region of Chernobyl," The Washington Post, March 25, 1995: "The rate of thyroid cancer in a region north of the Chernobyl nuclear plant is nearly 200 times higher than normal, according to research published in the British Medical Journal. Scientists from Russia, Ukraine, Belarus and the World Health Organization said abnormally high rates of thyroid cancer in children had been detected farther away in the northern Ukraine and parts of Russia.

... The cancer has appeared most in children because they are more sensitive to radiation and their thyroid glands are smaller, so a given amount of radioactive iodine represents a larger dose for a child's thyroid gland than for an adult's.

... In Gomel, a city in Belarus 70 miles north of Chernobyl, 143 cases of thyroid cancer were diagnosed between 1991 and 1994 in children under 15, the scientists said. That was a rate of 96.4 per million, compared with the normal rate of 0.5 per million."

radiation-caused thyroid disease entails much more than "a few days off." In Poland, on the other hand, where KI was administered to 97% of the nation's children, there has been no similar increase in thyroid cancer. The Polish example is proof positive of the benefits of a well-prepared KI program.²¹

In view of the grave medical news from the former Soviet Union, the United States Government is currently spending many millions of dollars -- some of it supplied by the NRC -- to study radiation-caused thyroid cancer in Ukraine and Belarus. Announcing a \$15 million, 15-year program that will follow 70,000 children in Ukraine, the Department of Energy declared, in a June 13, 1995 press release, that the studies "provide a unique opportunity to understand the thyroid cancer risk of exposure to radioiodine." The DOE press release explained: "The release of radioiodine is likely to figure prominently in any nuclear power plant disaster and knowledge of its carcinogenic potency is inadequate, especially in children."

In addition, the U.S. Government has spent generously to bring Ukrainian doctors to this country for training in thyroid surgery, because mishandled operations can mean damaged nerves and larynxes, and children rendered permanently mute. There could not be a better example of wise and humane foreign aid.

G. Post-Chernobyl developments on KI policy.

The Chernobyl accident demonstrated beyond the shadow of a doubt that potassium iodide worked; that it was no mere "amulet," as one of the briefers had scornfully described it to the Commissioners; and that countries which failed to stockpile and distribute it could find themselves with serious public health problems on their hands. The NRC staff, however, was not immediately ready to acknowledge that the new information from Chernobyl called for a revision of U.S. policy.

In early 1989, the NRC issued NUREG-1251, "Implications of the Accident at Chernobyl for Safety Regulation of Commercial Nuclear Power Plants in the United States," in which it concluded that the Chernobyl experience did not suggest a need for changing U.S. policy on KI. "Evacuation is generally feasible," it said, "and when carried out is more effective in dose reduction than administration of KI, since it can reduce the dose for all body organs and not merely the thyroid gland. ... The apparently

²¹ See Nauman & Wolff, footnote 5 above.

successful use of KI at Pripjat [a city close to Chernobyl] does not alter the validity of guidance that recognizes that evacuation of the general public in the affected area could result in a greater overall dose reduction."²² It is worth noting that no claim was made that evacuation was always feasible, just "generally" feasible.

H. The NRC reconsiders the KI issue.

In June 1989, in accordance with NRC procedures, I filed a "Differing Professional Opinion" urging a change in policy on potassium iodide. In order to allow the reader to understand any bias that I might bring to the issue, I made clear my own personal interest: in 1973, when I was 26, I had surgery for a malignant thyroid tumor, the probable result of x-ray treatment for enlarged tonsils and adenoids when I was two years old. In 1988, my doctors detected a recurrence, which required five radiation treatments over a three-year period to be eradicated.

On November 27, 1989, the American Thyroid Association wrote to the Commission, urging KI stockpiling on a nationwide basis. In 1990, the NRC announced that it was reconsidering the existing federal policy.²³ While the issue was under consideration at NRC, the World Health Organization's "Working Group on Strategy for Public Health Action in Relation to Nuclear Emergencies" issued a report stating that "implementation of [KI] prophylaxis is critical," and stating: "Stocks of iodine should be stored strategically at points including hospitals, schools, and fire and police stations."²⁴

In April 1992, a contractor under the sponsorship of NRC's Office of Research issued a report which included a revised cost-benefit analysis of the use of potassium iodide. To the credit of the contractor and the NRC staff, this included a serious attempt to rectify the past downplaying of the consequences of radiation-caused thyroid disease. As far as its weighing of costs and benefits, however, it was bound by the staff's estimates of accident probabilities. Using those figures, the report concluded that stockpiling continued to be non-cost-effective, but that the difference between costs and benefits was

²² NUREG-1251, Section 4.2.3, "Assessment."

²³ 55 Fed. Reg. 39768 (September 28, 1990).

²⁴ World Health Organization, EUR/ICP/CEH 102(S), Section 4.3.3. (1991).

significantly narrower than had been calculated by the NRC staff in the early 1980's. For the population within a 5-mile radius, "the cost-benefit ratio for use of potassium iodide by the general public approaches a value of two," the staff reported in November 1993.²⁵

In December 1993, an industry trade group, the Nuclear Management and Resources Council, sent a "White Paper" to the Commission arguing against any change in current KI policy. (It was the only group to do so.) The White Paper suggested that a change in policy would cause members of the public to "want to know if the federal policy is being changed because the plants are less safe." It added: "Public confidence in the technology could be affected by the decision."²⁶

The industry White Paper also quoted Dr. David Becker, an eminent thyroidologist who is currently heading the NRC-sponsored research into thyroid cancer in Belarus, in such a way as to make it appear that he opposed KI stockpiling. This was taking a

²⁵ SECY-93-318, p. 4. Thus by these calculations, KI almost pays for itself for the closest-in populations. This averaged figure does not take into account either the difference in safety between plants of different designs or the wide margin of error (a factor of 100) in the estimates of accident probability. If accidents are 100 times more probable than estimated, then KI for these nearby residents will pay for itself 50 times over, by the NRC staff's own calculations. My contention, however, is not that KI will necessarily pay for itself. Rather, it is that the uncertainty in the actual probability of major accidents makes these cost-benefit calculations of little value, and argues for letting prudence and good judgment drive the decision on KI.

²⁶ "Review of Federal Policy on Use of Potassium Iodide," Nuclear Management and Resources Council (December 1993), p. 8. The industry's argument echoes the claim of environmentalists and residents of the Three Mile Island area, in the early 1980's, that the NRC was required to consider the fears of the local population, and the probable "psychological impacts" on them, in determining whether to allow resumed operation of the Three Mile Island Unit 1 reactor. The NRC, supported by industry, took the position that a scientific and technical agency should base its decision on the best available scientific and technical evidence, not on people's fears. A unanimous Supreme Court upheld the NRC, after I briefed, argued, and lost the case in the D.C. Circuit Court of Appeals. Metropolitan Edison Co. v. People Against Nuclear Energy, 460 U.S. 766 (1983), reversing People Against Nuclear Energy v. NRC, 678 F.2d 222 (D.C. Cir. 1982).

chance, in light of the fact that Dr. Becker was one of the signers of the November 1989 American Thyroid Association letter urging KI stockpiling, and the New York Times had published a letter from him to the same effect. After Dr. Becker protested, a senior NRC official sent a letter of rebuke to the industry group, declaring that its characterization of Dr. Becker's views was "completely contrary" to his actual position. Copies were sent to Dr. Becker and the NRC's Public Document Room.²⁷

I. The NRC staff backs KI stockpiling, but its proposal for a change in policy is blocked when the Commissioners deadlock.

On March 29, 1994, the NRC staff declared its support for KI stockpiling. In its final memorandum to the Commission on the subject, it wrote:

Although a reactor accident requiring KI is unlikely and KI is only effective as a protective measure for the dose to the thyroid due to radioactive iodine, the cost to purchase and stockpile amounts sufficient to administer to populations within five miles of operating nuclear power plants is relatively low. [In a footnote, the staff estimated the cost at \$.10 per person per year.] Consequently, it appears prudent to stockpile KI for limited populations located close to the operating nuclear power plants." [Emphasis added.]

The staff reported that it had engaged in dialogues with FEMA and the Department of Health and Human Services, and that the two agencies "would cooperate with the NRC in working toward adoption of a revised federal policy on KI." The staff proposed that the federal government buy the drug and make it available through FEMA to the states, which would be encouraged (but not compelled) to stockpile it.

On April 20, 1994, while the issue was pending before the Commissioners, Senators Alan Simpson, Republican of Wyoming, and

²⁷ Letter of June 1, 1994, from James L. Milhoan, Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to J. Phillip Bayne, President and CEO, Nuclear Energy Institute (NEI). NEI was the successor organization to NUMARC, which was in turn the successor to the Atomic Industrial Forum of the early 1980's.

²⁸ SECY-94-087, "Addendum to SECY-93-318 Re-evaluation of Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant," at 2.

Joseph Lieberman, Democrat of Connecticut, wrote a concise and forceful letter to the Commission, urging that U.S. policy on potassium iodide be brought into line with expert opinion and international practice. After marshaling the many arguments for KI, they dealt with the claim that KI stockpiling could result in "negative public perception." They wrote:

[N]o evidence has been provided that any of the existing policies in other nations or in the states that provide for the use of KI by the general population has caused any undue panic or apprehension to the general public. Moreover, the federal government has a moral responsibility to provide the public with complete and accurate information regarding the risks from federally-licensed activities and ways in which those risks may be reduced.²⁹

When the staff proposal came to a vote, however, the four Commissioners divided 2 to 2,³⁰ and under NRC internal procedures, a tie vote on a proposal means that it fails. There was, therefore, no decision on the merits of the NRC staff's recommendation.

J. KI and the federal government -- current status.

The tie vote on the staff's proposal for a change in policy seems to have been misunderstood completely by an interagency committee considering the KI issue. The February 1995 issue of "CRCPD Newbrief," the newsletter of the Conference of Radiation Control Program Directors, reported that at a December 1994 meeting of the Federal Radiological Preparedness and Coordination Committee (FRPCC), an ad hoc subcommittee on KI presented and discussed a report on the drug. According to the newsletter, "the subcommittee indicated that there is a lack of new data challenging the [1985] FRPCC Federal Policy" on KI. The story continued: "A lack of justification for a federal stockpile was identified by the subcommittee. There is also a lack of support for federal stockpile initiative by the states and the primary

²⁹ A copy of the letter is attached to this petition.

³⁰ The Commission's "Staff Requirements Memorandum" of May 6, 1994 recorded Commissioner Rogers's vote in favor of the staff recommendation but was silent as to the individual positions of the other three Commissioners. Commissioner Rogers is the only one of the four still on the Commission.

federal regulatory agency [NRC]."³¹

The FRPCC subcommittee's position is all the harder to fathom in light of the publication by FEMA in September 1994 of a proposed "Federal Radiological Emergency Response Plan"³² which expressly envisions the use of KI during radiological emergencies. Clearly, this implies that the authors of the Plan recognize the drug's usefulness. Under the Plan, NRC will be the "Lead Federal Agency" during emergencies at nuclear power plants, and its duties will include providing

...advice to State and local governments on measures that they should take to avoid or reduce exposure of the public to radiation from a release of radioactive material. This includes emergency actions such as sheltering, evacuation, and prophylactic use of iodine."³³

The Plan further provides for an interagency "Advisory Team for Environment, Food, and Health" to help the "Lead Federal Agency" formulate its advice, by providing, among other things,

Guidance on the use of radioprotective substances (e.g. thyroid blocking agents), including dosage and projected radiation doses that warrant the use of such drugs."³⁴

Thus the new Plan envisions that in an emergency, the interagency panel will advise the NRC on when KI should be used, the NRC will then advise the state and local governments, and the

³¹ One has to wonder where the subcommittee has been getting its information if it is unaware of any "new data challenging" the 1985 policy. The subcommittee might begin by reading the American Thyroid Association's letter of 1989; the March 1994 memorandum by the NRC staff, endorsing a change in federal policy; the April 1994 letter from Senators Simpson and Lieberman, summing up the arguments for KI stockpiling; the International Basic Safety Standards, adopted in 1994 with U.S. Government support; and the newspapers, which regularly carry articles on Chernobyl-related thyroid disease in the former Soviet Union.

³² 59 Fed. Reg. 46086 (September 6, 1994).

³³ 59 Fed. Reg. at 46091.

³⁴ Id.

states and localities will then administer the drug. What the Plan's authors either do not realize or do not choose to mention is that in a real emergency there will be no KI to give out, thanks to the current federal policy on the drug."

Also in 1994, the Board of Governors of the International Atomic Energy Agency, with U.S. Government support, adopted new "International Basic Safety Standards." These standards represent the consensus of the world's experts on radiation safety. With regard to emergency planning, they provide, among other things: "Intervention levels for immediate protective actions, including sheltering, evacuation, and iodine prophylaxis, shall be specified in emergency plans...." "Thus the international radiation protection community, like the Kemeny Commission in 1979 and the short-lived draft federal policy statement of 1982, recognized that effective preparedness for radiological emergencies meant having three arrows in the quiver, not just one or two.

³⁵ Several years ago, Dr. Jerome Halperin, who as an FDA official was involved in the effort to obtain KI during the Three Mile Island accident lamented in a medical journal article that the nation was still in a pre-TMI state of readiness for emergencies requiring the drug. "Potassium Iodide as a Thyroid Blocker -- Three Mile Island to Today," DICP, The Annals of Pharmacotherapy, Vol. 23, May, 1989. His statement was accurate at the time he wrote and remains so today.

³⁶ International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources (interim edition), International Atomic Energy Agency (Vienna, 1994), at 73.

III. Argument

1. The U.S. Government cannot rationally conclude that it is worthwhile to spend \$15 million to study radiation-caused thyroid cancer in Ukraine, but not worthwhile to spend a much smaller sum to prevent radiation-caused thyroid cancer in this country.

The project now underway to study thyroid cancer in Ukrainian children will cost the United States about \$200.00 for each child studied. At the same time, the U.S. Government refuses to spend \$.10 per child to prevent thyroid cancer in American children. To make clear, I am not criticizing the expenditure on the study in Ukraine, I applaud it. But I question whether, at \$15 million dollars, it is 50 or 60 times more valuable to the American people than would be a national potassium iodide stockpile, costing a few hundred thousand dollars, that could prevent large numbers of cancers, some of them fatal, in the event of a serious accident. The United States should be able to afford both.³⁷ The NRC staff has estimated that KI is so cheap that buying the drug would cost less than continuing to study whether it is cost-effective to buy it.

Nuclear accidents can happen, here as well as abroad. If accidents can happen, that means that given enough time, eventually they will happen. If a major accident ever occurs in this country, we do not want American children go through what the children of Belarus, Ukraine, and Russia are suffering today. A stockpile of KI can help assure that they do not.

This is not a radical proposition by any means. As noted above, all the relevant agencies of the United States Government, including the NRC, initially agreed with the Kemeny Commission recommendation that KI stockpiling was sensible, prudent, and worthwhile. The wisdom of that recommendation was confirmed by Chernobyl in 1986. Whatever the reason for the Government's abrupt reversal late in 1982, it was a serious mistake, and correction is long overdue.

³⁷ It need hardly be added that if there is ever a major nuclear release in this country, we will spend hundreds of millions of dollars identifying, treating, and compensating harm that might have been prevented by the timely expenditure of that few hundred thousand dollars.

2. Evacuation is not necessarily the protective measure of choice in every emergency, and even when it is the preferred option, it is not always feasible.

The 1985 federal policy statement, declaring that KI stockpiling would not be worthwhile, explained: "This is based on the ability to evacuate the general population and the cost effectiveness of a nationwide program which has been analyzed by the NRC...."

There are two problems with the underlined portion of this statement. It implies (1) that evacuation is necessarily the protective measure of choice in every emergency, and (2) that authorities would always have the "ability to evacuate the general population." Both propositions are false, and the existing policy may therefore give states and the public a false sense of security.

As the Kemeny Commission report explained (see p. 8 above), different types of accidents, and the particular circumstances presented, may call for different protective measures. A KI stockpile assures that responsible authorities have an additional type of protection in their arsenal.

The NRC has never claimed, nor could it claim, the "ability to evacuate the general population" whenever a serious accident occurs. On the contrary, it has repeatedly made clear that a finding of adequate emergency planning does not translate into a guarantee that the entire affected public can necessarily be evacuated. The most NRC that asserts (for example, in NUREG-1251, issued in 1989) is that evacuation is "generally" feasible. In the real world, unexpected things happen, such as severe weather conditions or blocked highways, that can make complete evacuation impracticable.

This means that sometimes, either by choice or necessity, authorities may be sheltering people or telling them to remain indoors rather than evacuating them. Any time that people are sheltered or told to stay indoors, it may be desirable to administer KI. In addition, any time that evacuation routes may take people through areas of radiological contamination, it makes sense to give them KI. Finally, any time (as in the case of Chernobyl) that there is a large airborne release high in the atmosphere, with uncertainty about where the radiological contamination will descend, it makes sense to be ready to administer the drug, since one cannot know whom to evacuate. Obviously, you do not have the option of administering KI if

there is none to administer."³

The opponents of KI often make the argument that to be in favor of KI stockpiling amounts to downplaying the importance of evacuation. Evacuation protects the whole body, they say, whereas KI protects only the thyroid gland, so to support stockpiling is to indicate a willingness to leave the rest of the body at risk from radiation, thereby diminishing public protection. This argument is factually incorrect, illogical, and disingenuous. The advocates of KI stockpiling, from the Kemeny Commission through the International Basic Safety Standards, have always envisioned the drug as complementing other emergency planning measures, not replacing them. There is no way that the availability of KI could increase risk to the public. Would the existence of a supply of pills on a shelf in local schools and firehouses cause all the public officials responsible for managing radiological emergencies to forget about evacuation as an option if an emergency occurred? Would it impede an evacuation? Of course not.

3. The decision on stockpiling KI should turn on whether, given the enormous consequences of being without it in a major accident, it is a prudent measure, not on whether the drug will necessarily pay for itself over time.

The opponents of KI have framed the issue in terms of whether the drug is "cost-effective" -- that is, whether it would pay for itself over time in terms of reduced medical expenditures to treat radiation-caused thyroid disease. The implied premise is that if KI is not cost-effective in dollar terms, it is therefore not worth having.

That premise, however, is false. KI, like all other emergency planning measures, represents a kind of catastrophic-coverage insurance policy, offering protection for events which, while they occur only rarely, have such enormous consequences when they do occur that it is sensible to take special

³ Compare the point made by Commissioner Rogers, in voting for the staff's recommendation, as recorded in the NRC Secretariat's "staff requirements memo" of May 6, 1994: "Commissioner Rogers believes that, in order for FEMA, State or local authorities to have a viable option for a KI program, it would be prudent for the U.S. government to assure the availability of a supply of KI."

precautions." Health and life insurance policies are not intended to be cost-effective for the average purchaser. (If they were cost-effective, every insurance company would go bankrupt.) Does that mean that people are foolish to carry insurance? Of course not; it is the people who fail to carry insurance who are considered foolhardy. In addition to buying insurance, we spend money on countless other preventive measures in everyday life -- vaccinations for our children, smoke detectors and fire extinguishers for the home, a first aid kit for the car -- because they are sensible, not because we necessarily expect them to pay for themselves.

The best analogy to KI may be the lifejackets that ferryboats carry. We start with the assumption that ferryboat sinkings are unlikely, and we readily acknowledge that if an accident does occur, it is better to leave the ship in a lifeboat than bob in a lifejacket in the water. But sometimes things do not happen in real life the way they happen in drills. If there is no lifeboat available when the ferry sinks, the lifejacket may keep you from harm while waiting to be rescued, and if no lifeboats can be launched, you are better off with a lifejacket than with nothing at all. So we equip our ferries with lifejackets; we do not spend more money than the lifejackets themselves would cost studying whether to buy them; and we do not find the ferry operators writing White Papers to prove that if passengers knew that there were lifejackets on board, they would be too frightened to travel by boat.

4. The estimates of KI's "cost-effectiveness" all depend on estimates that are no more than informed guesses about the probability of severe accidents.

The cost-benefit analysis upon which the current KI policy is based relies on certain assumptions about the probability of severe accidents. Those assumptions need to be recognized for what they are: informed guesses, not hard facts. The NRC's cost-benefit analysis of the early 1980's was based on the assumption that a severe accident with a major release of

³⁹ At the 1983 Commission meeting on KI, one of the briefers compared KI to an insurance policy which, when you read the fine print, covers only death by stampeding elephants. The problem with this analogy is that the United States has never to my knowledge experienced an elephant stampede, and it is never likely to. The United States has, however, experienced the partial meltdown of a nuclear power plant (at Three Mile Island), and it could do so again.

radioactivity could occur in this country only once every 1000 years (with 100 reactors operating). But the all-important margin of uncertainty was huge: the agency acknowledged that accidents might be as much as 100 times more likely than that. In the past, optimistic predictions have not always been borne out by events. The Three Mile Island accident was also considered highly improbable, until it happened.

If it were really true that serious accidents with a release of radioactivity "can't happen here," then there would be good reason not only not to reject stockpiling of KI, but also to dispense with all the rest of emergency planning. One could then ignore Chernobyl, and disregard the use of KI in the rest of the developed world, by saying that while foreign reactors may suffer serious accidents, ours will not. But the NRC has never claimed that accidents in this country are impossible. In 1985, the same year that the current policy statement was adopted, the NRC Commissioners were advising the Congress that the estimated likelihood of a core melt accident at a U.S. reactor by the year 2000 was 45%.⁴⁰

Granted, not every accident results in a core melt, and not every core melt accident necessarily leads to offsite releases. One can be quite sure, however, whenever there is a serious accident, authorities will be looking for KI just in case it progresses to the point of a large offsite release. (We can assume that for every catastrophic accident, there will be a number of these lesser accidents.) Thus it is not sufficient to say that accidents with major offsite releases occur only rarely; the more relevant question is the chance of an accident serious enough to make authorities start hunting for a supply of KI.

5. If KI is not cost-effective, the rest of nuclear emergency planning is probably not cost-effective either.

The argument that KI should not be part of radiological emergency planning because it is not "cost-effective" carries the implication that those measures which are currently part of NRC-required emergency planning (sirens, exclusion zones, periodic emergency exercises, etc.) have been found to be cost-effective. This is not the case. KI is the only emergency planning measure to have been scrutinized with a cost-benefit analysis. The NRC's Advisory Committee on Reactor Safeguards pointed out long ago that all the other elements of the NRC's emergency planning requirements (such as sirens and periodic emergency exercises)

⁴⁰ The New York Times, April 17, 1985.

were put in place without a cost-benefit analysis and might well not pass that test." If serious accidents are really possible only every one or two thousand years, it is unlikely that any element of current nuclear emergency planning could be found "cost-effective," in the sense of being likely to pay for itself over time. Does that mean that the United States should leave the public at even greater risk by declaring that for American reactors, no emergency planning whatsoever is necessary? Of course not.

6. Cost-benefit analysis is a technique that needs to be applied with good sense, especially where public health measures are concerned.

Cost-benefit analysis, as valuable a tool as it can be when properly applied, needs to be performed with a measure of good sense, which includes a recognition that sometimes, costs and/or benefits may not lend themselves to quantification in dollar terms. This is particularly true in the area of public health.

Here, the evaluation of KI that preceded the 1985 federal policy statement was of a kind to give cost-benefit analysis a bad name. Strictly limited to economics -- the dollar costs of KI pills on the one hand, the dollar costs of having radiation-caused thyroid disease on the other -- it wholly ignored the quality-of-life impacts of thyroid cancer and other radiation-caused diseases.

Common sense tells us that if given a choice between a case of disease prevented and a case of disease cured, we would all prefer the former, even if the cure did not cost us a penny. But the cost-benefit analysis of KI proceeded from the assumption that there was no difference in desirability between prevention of radiation-caused thyroid disease and cure; thus the only factor to be considered in evaluating KI was the difference in cost. The old proverb that an ounce of prevention is worth a pound of cure went out the window, as the U.S. Government

"The ACRS said: "The risk-benefit analyses conducted by the NRC Staff on this subject do not appear to be compatible with (or comparable to) approaches used in evaluating other aspects of nuclear emergency planning. For example, if the same evaluations were made, would there be justification for the conduct of emergency drills or the installation of warning sirens? Similarly the question could be raised as to whether there would be justification for population evacuations." Attachment to SECY-83-362 (August 30, 1983).

determined that instead of spending money to prevent radiation-caused thyroid disease, society should spend its money treating the disease if and when it occurred.

Any child knows that the negative impacts of illness are not limited to the economic costs. Any parent knows that people do not immunize their children against polio and diphtheria primarily to save money. In the real world, people pay to immunize their children against diseases first and foremost to spare them the misery and the danger that go with these illnesses.

But the cost-benefit analysis of KI ignored that obvious point, and as a result, it was valueless from the start. Indeed, it was worse than valueless, because it provided a rationalization for ignoring the Kemeny Commission's sensible recommendation in favor of KI stockpiling. The non-economic impacts of illness may be difficult to translate into dollar terms, but that does not mean that they can be ignored.

7. The existing policy on KI was defective from the start, as it was based in part on inaccurate information provided to the NRC Commissioners.

Decisionmakers who must weigh costs and benefits also need accurate data. The transcript of the 1983 staff briefing makes clear that the information provided to the NRC Commissioners seriously understated the significance of radiation-caused thyroid disease and thereby understated to an equal degree the value of KI. The briefers' central failure was to mention that when referring to "nodules," they were not taking into account the 40% of nodules that would be cancerous. It is as though staff members of the Department of Transportation informed the Secretary that airbags were of no value in "collisions" without mentioning that their definition of the word excluded every collision more serious than a fender-bender. Whatever additional information the Commissioners later received on the subject of thyroid disease, it is not at all clear that the Commission had any idea of the real nature of post-accident thyroid disease at the time they adopted an anti-KI position. Certainly, the public never received notice that the information provided at the 1983 meeting was erroneous.

8. Existing policy purports to leave the judgment on stockpiling KI to the states, but assures that the states do not have an adequate basis for making informed decisions.

In theory, the existing federal policy on KI leaves the

decision on stockpiling to the states. Since 1983, however, the federal government, and NRC in particular, have failed to provide the states with sound technical advice on the subject. Without accurate and current information on KI -- including the Chernobyl experience and the consensus of international experts -- states cannot make an informed judgment.

In their April 1994 letter to the Commissioners, Senators Simpson and Lieberman said pointedly that "the federal government has a moral responsibility to provide the public with complete and accurate information regarding the risks from federally-licensed activities and ways in which those risks may be reduced."

Since that time, however, the government's record on providing the public with "complete and accurate information" has actually taken a turn for the worse, with the publication in September 1994 of FEMA's "Federal Radiological Emergency Response Plan." As described above, at p. 22, the Plan provides that in an emergency at a nuclear power plant, an interagency Advisory Team will provide guidance on KI to the NRC, and the NRC will "provide advice to State and local governments on measures that they should take to avoid or reduce exposure to the public," including "sheltering, evacuation, and prophylactic use of iodine."

No state or local official or member of the public, reading this Plan, could possibly imagine that in a real emergency, there would be no iodine to administer. This raises a number of questions. If KI stockpiling is not worthwhile, why is administration of the drug one of the protective measures identified in the Plan? If KI is worthwhile, as the Plan implies, why isn't something being done to make sure that it is available? Does FEMA not know the actual state of KI preparedness?

The federal government cannot have it both ways. Either it should change the 1985 policy, and make the use of KI a viable option in a real emergency, or it should explain loud and clear why the United States has decided that KI will not be an option. What it cannot responsibly do is withhold protection, on the one hand, and on the other hand, represent to the public that this protection is already in place.

IV. The Remedy

The purpose of this petition, which takes the form of a rulemaking petition under 10 CFR § 2.802, is to raise the potassium iodide issue before the Commission and ensure that it receives a definitive resolution.

My specific request is for a minor change in the NRC's existing emergency planning rules, 10 CFR § 50.47. These rules include 16 planning standards by which emergency plans are to be evaluated. The tenth of these standards reads as follows:

(10) A range of protective actions have been developed for the plume exposure pathway EPZ [Emergency Planning Zone] for emergency workers and the public. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

I propose that the NRC amend this provision to read, "A range of protective actions, including sheltering, evacuation, and prophylactic use of iodine, have been developed..."

This language is taken verbatim from FEMA's September 1994 Federal Radiological Emergency Response Plan. If this change is adopted, the Plan will become an accurate description of emergency preparedness for radiological emergencies; the recommendation of the Kemeny Commission will at last be implemented; and the United States will be in compliance with the International Basic Safety Standards.

I suggest that the NRC also issue, either on its own or in conjunction with other agencies, a policy statement declaring that KI stockpiling is a sensible and prudent measure, necessary to assure that the drug will be available in the event of a major accident. (This policy statement could be modeled on the excellent draft statement of 1982, which regrettably was withdrawn.) This statement would make clear that KI, while no panacea, can be used in conjunction with evacuation and sheltering to maximize protection to the public.⁴²

⁴² I am not proposing house-to-house predistribution of KI, which I think would be ineffective and a source of confusion during an actual emergency. Rather, I am suggesting that state and local authorities have ready access to supplies of the drug so that they

can administer it if it is needed.

The policy statement would also state the willingness of the NRC to provide a stockpile of the drug to states and localities upon request (unless FEMA or some other federal agency is prepared to do so). In addition, the statement would support the Kemeny Commission's recommendation for the creation of regional stockpiles of the drug as a backup for emergencies.

This policy would mean negligible cost to utilities. Contrary to the apprehensions of the nuclear industry, it would not send a message that nuclear plants have suddenly become more dangerous; it would simply mean that the U.S. Government, figuratively speaking, was putting a first aid kit into the car, after having neglected to do so for far too many years. Would members of the public suddenly become newly frightened of nuclear accidents because KI is being stockpiled? As Senators Lieberman and Simpson pointed out, the presence of KI does not seem to have panicked the population in the places where it is stockpiled today, and there is no reason why it should. If the World Health Organization recommendation is followed, and KI is stored strategically in firehouses, hospitals, police stations, etc., few people are likely even to be aware that the drug is being stockpiled.

The amount of potassium iodide stockpiled around each nuclear plant would not be great. Most nuclear plants are sited away from large concentrations of population in order to keep down the risk to the public. In an emergency, the drug might be needed in a wider area than just the immediate radius around the plant (at Chernobyl, for example, much of the radioactive iodine came to ground far downwind), but the existence of regional stockpiles would mean that the nation had a backup supply to draw upon in case of need.

If there should ever be a nuclear accident in this country serious enough to make authorities need KI, or even consider its use, and there was no KI to be found, what would the American people say? The anger and recrimination afterwards would be enormous, both for the failure to protect and the failure to inform. NRC, having promised in 1979 to put a KI program in place and then not done so, would have the most to answer for, especially in light of the the wealth of recent data from Chernobyl on thyroid effects and the 1994 recommendation of its own technical staff in favor of stockpiling. FEMA would be in the unenviable position of having to explain why its 1994 Plan implies not only that KI is valuable in emergencies, but also

can administer it if it is needed.

that it is currently available.

But pointing fingers after the fact will do no good to any child who got a dose of radioactive iodine in the thyroid because KI was lacking when it was needed. We cannot afford to wait until another accident or near-accident, and the resulting hue and cry, compel a change of policy. There is ample evidence now that the current policy is ill-founded, irrational, and dangerously complacent. The time to put a lock on the barn door is before the horse is stolen. If it should turn out that no attempt to rob the barn is made in our lifetimes, so much the better -- it's a very cheap lock.

Today, the Nuclear Regulatory Commission has the opportunity and the responsibility to resolve the KI issue sensibly and straightforwardly, as the NRC staff proposed doing in 1994. There is no good reason why American children should continue to be unprotected with KI, when the governments of other developed countries around the globe provide this cheap and effective protection for their children as a matter of course. The NRC staff has pointed the way, and the Commission and the Federal Government should follow.

Attachment:

Letter of Senators Alan K. Simpson and Joseph I. Lieberman,
April 20, 1994

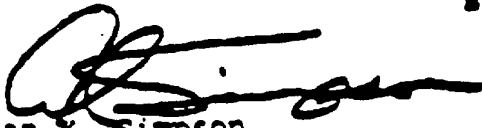
A recent cost-benefit study of this issue conducted for the NRC indicates that the costs of stockpiling KI for people who live within five miles of a nuclear power plant are minimal--approximately ten cents per person per year. This means that for a typical population of 10,000 people living within five miles of a nuclear power plant, it would cost approximately \$1,000 to make KI available for distribution. The NRC staff projects that the cost of stockpiling KI for everyone in the country within five miles of a nuclear power plant would be on the order of several hundred thousand dollars per year. This is only a small fraction of the expenses already spent on emergency planning. As the NRC staff has noted, "[c]osts in this range present no significant barrier to stockpiling and are probably less than the cost of the continued studies."


Some concern has been expressed that public education on the use of KI may result in a potentially significant negative public perception. However, no evidence has been provided that any of the existing policies in other nations or in the states that provide for the use of KI by the general population has caused any undue panic or apprehension to the general public. Moreover, the federal government has a moral responsibility to provide the public with complete and accurate information regarding the risks from federally-licensed activities and ways in which those risks may be reduced.

In sum, therefore, KI can be an extremely effective countermeasure to prevent damage to the thyroid in the event of a radiological emergency. It can also be made available for the general population living near a nuclear power plant for minimal costs. The NRC should revise its policy to provide this additional potential protective measure for nuclear emergency planning.

We thank you for your time and consideration.

Sincerely,


Alan K. Simpson
Ranking Minority Member
Subcommittee on Clean Air
and Nuclear Regulation


Joseph I. Lieberman
Chairman
Subcommittee on Clean Air
and Nuclear Regulation

DOCKETED
USNRC

November 11, 1997

Mr. John C. Hoyle, Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

97 NOV 12 P4:17

OFFICE
RULE
ADJUTANT

Re: Amendment to Petition for rulemaking (PRM-50-63)

Dear Mr. Hoyle:

At the Commission meeting on potassium iodide held on November 5, 1997, Chairman Jackson asked me whether I could submit, within the week, language reflecting the modified position that I outlined during the meeting. Attached to this letter is a draft of a proposed rule change, accompanied by a statement of considerations explaining the change.

Under the approach I outlined in the meeting, the NRC would "require that consideration of potassium iodide be given in the formulation of emergency plans," but "would not ram potassium iodide down the throat of a state that emphatically rejected it." I made clear that I was asking for two things: a statement clearly recommending stockpiling of KI as a "reasonable and prudent" measure, and a rule change identifying what is meant by a "range of protective actions" (i.e., evacuation, sheltering, and KI) and requiring their consideration.

In the meeting, I sometimes referred to the "reasonable and prudent" statement as a "statement of policy," while elsewhere I talked about "clarification which could readily be done in the statement of considerations for such a rule." (At one point, Commissioner Diaz observed, and I agreed, that I was proposing that the Commission, in a "public statement or a rule," express the belief that stockpiling was a prudent measure.) In short, there may have been ambiguity as to whether I was seeking two separate documents -- a rule change and a policy statement explaining it -- or just one, a rule change with policy stated and explained in the statement of considerations. Plainly, the latter makes more sense (in any event, to propose a rule change, the NRC would have to offer its reasons for doing so) and seems most consistent with the Commission's interest in resolving the KI issue in an efficient and timely way.

In the attached proposal, which represents an amendment to my petition, the Commission's expression of policy therefore would take place in the context of the rule change, i.e., in the statement of considerations. I trust that no one will view this as any deviation from what I was proposing in the meeting.

I realize that it is an ancient negotiating ploy to press for more than you think you can possibly get, as a prelude to bargaining. The fact that this proposal does not do that, but instead is squarely in line with what I described

ENCL 1

on November 5, is an indication that I take this amendment of my petition very seriously, without game-playing. I would like as much as anyone to see this protracted process brought to closure, with broad consensus acceptance. Accordingly, I have tried to produce a solution that satisfies the NRC's obligations to protect and inform the public, that does not encroach unnecessarily on state prerogatives, and that enables the Commission to put a difficult and divisive issue behind it.

I have also tried in this draft Statement of Considerations to present the KI issue in such a way that no one can accuse the Commission, if it adopts this approach, of being alarmist, or of failing to put safety issues in their proper perspective. Moreover, although I have often, in past submissions, discussed troubling past events, such as those I referred to in the November 5 meeting, I have omitted these historical matters from the proposed Statement of Considerations that I am offering today. This reflects a conscious decision to look forward, not to the past, in the recognition that for a health and safety agency, the central question must always be: What makes sense today, in light of what we know now?

I believe that if the approach I am proposing is accepted, it would be viewed as so patently reasonable that if challenged legally, it would be sustained by any reviewing court, whether the challenge came from those who thought it went too far or from those who thought it did not go far enough. In the memorable words of the late Judge Harold Leventhal of the U.S. Court of Appeals for the D.C. Circuit, "When agencies make good sense, courts are loth to find that it is not good law." On issues of litigation risk, however, the Commission should of course rely on the General Counsel and the Solicitor for advice.

A rulemaking of this kind need not consume significant resources. Though it was suggested at the November 5 Commission meeting that a rulemaking would take two additional years (i.e., for a total of more than four years since the filing of the petition), this seems exaggerated. It is a matter of public record, for example, that the Commission's last major emergency planning rulemaking, the "realism" rule of 1987, did not require any two years, though it involved many extremely complicated issues and elicited more than 38,000 comments (including many duplicates), all of which had to be read. In that case, a 66-page memorandum to the Commission was prepared in which the issues and comments were analyzed and discussed in detail, with the arguments on both sides fairly presented. A Commission briefing was also held at which the merits of the competing arguments were discussed at length. In the end, the analysis and the final rule were sufficiently airtight, both as policy and as law, that none of those dissatisfied with the rule -- and there were many -- decided to seek judicial review. The entire process, from proposed rule to final rule, took 9 months.

A KI rulemaking along the lines I am proposing would be a minor, not a major rulemaking. It would involve fewer issues and, to judge from the 60 or so comments filed on the petition, would probably elicit comments numbered in the dozens, not in the tens of thousands. If the staff turns to the KI rulemaking with a will, and it is given a firm deadline for turning it around, there is no reason why it could not be completed in significantly less time than the nine months that the "realism" rule required.

I was also asked to provide for the record the citation to an Environmental Protection Agency document that I referred to. The document is the Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, EPA-400-R-92-001, published by EPA in May, 1992. On November 11, 1995, I wrote to you, as Secretary of the Commission, that at the time I filed my rulemaking petition two months earlier, I had been unaware of this document. I therefore wished "to draw the Commission's attention to this document and to ask that this letter and its attachment [a detailed discussion of the EPA Manual and its implications for the KI issue] be considered as a comment supplementing my petition." This letter and its attachment are in the rulemaking docket as comment no. 5, docketed November 13, 1995.

Finally, I was asked to provide a suggested markup of the draft Federal Register notice proposed to the Commission in SECY-97-124. First, I would like to put the notice in context. SECY-97-124 asked for Commission approval of an approach, not of the appended Federal Register notice.¹ Neither the SRM nor the vote sheets of Chairman Jackson or Commissioner Dicus, who voted for Option 2, referred specifically to the draft Federal Register notice in Attachment 1. Nor did the Commission's Staff Requirements Memorandum of June 30, 1997. Thus I do not think that the Commission's vote for Option 2 should be regarded as a vote for the Federal Register notice as drafted by the NRC staff, and my criticisms of the notice are directed at the NRC staff, not at the Commission.

The NRC staff has already acknowledged, at the November 5 Commission meeting, that SECY-97-124 misinformed the Commission as to one element of the procedural history of the KI issue: it was the NRC, not FEMA, whose opposition to stockpiling helped produce -- almost -- the reaffirmation of the 1985 policy in 1995. The same lack of perspective (to use the mildest term possible) that was responsible for that misstatement can be seen in the staff's

¹ All that SECY-97-124 had to say about the draft notice was the following, at p. 10: "Attachment 1 contains a proposed Federal policy on KI that reflects the key elements of this option. It incorporates changes recommended by the FRPCC's Subcommittee on Potassium Iodide, acknowledges the developments in the area of NBC events regarding KI but does not alter the current emergency planning requirements."

draft Federal Register notice, both in the selection of the facts it chooses to report and in its overall tone, which is heavily slanted against KI.

I would therefore be remiss if I did not candidly advise the Commission that the draft Federal Register notice, if issued in its present form, is likely to bring nothing but opprobrium to the NRC and to FEMA. In large measure, the notice's failings speak for themselves. What is one to say about a notice that does not get around until page 8 to mentioning that the prevention of cancer is the primary purpose of using KI? What is one to say about a purported history of the KI issue that describes how the FRPCC almost reaffirmed the 1985 KI policy two years ago, but does not mention Chernobyl, even though that accident has produced an extraordinary wealth of new data both on radiation-caused thyroid cancer and on the safety and efficacy of KI?

Can the NRC staff really mean to suggest that it is important that the public learn all about petty bureaucratic maneuverings that occurred in 1994 and 1995, but nothing about the upsurge of childhood thyroid cancer taking place now in the former Soviet Union? This is the way to court not merely criticism, but also ridicule and contempt.

I have tried, therefore, to offer suggestions to make the notice more informative to the reader, more balanced in substance and tone, and less susceptible to being quoted out of context.

For example, I think it is unwise for the NRC and FEMA to embrace too vigorously the line, "no new information that seriously challenges the bases for the 1985 recommendations." It is worth asking the staff to explain exactly what that line means. The ordinary reader is likely to interpret it to mean that there is no new information bearing significantly on the KI issue. That, however, would be demonstrably untrue. Rather, the sentence seems to mean that the 1985 policy was based on a cost-benefit analysis which showed that KI was not cost-beneficial, and the Government has not received any new information suggesting otherwise.² But of course, the discussion of KI in the last several years, including the Government's decision to stockpile the drug for NBC terrorist events, has all been based on prudence, not on cost-benefit considerations.

If the Commissioners or the EDO were sometime called upon to explain this sentence, and it turned out to mean what I suggest it seems to mean, would

² It would not even be correct to say that there is no new information challenging the cost-benefit analysis that was the basis of the 1985 "not worthwhile" policy. The reanalysis of costs and benefits in 1992 showed the ratio of costs and benefits to be almost equal for close-in populations, whereas the cost-benefit analysis that underlay the 1985 policy showed an extremely high ratio of costs to benefits.

they feel comfortable that the notice had done a good job of informing the public? Or would the sentence seem, on examination, to be a cleverly worded way of disguising the fact that an enormous amount of new information bearing on the value of KI has emerged since 1985? I believe that Government agencies should be careful to speak so clearly and forthrightly on issues like these that they never leave themselves open to the charge, just or unjust, of having used words artfully to create a misleading impression.

At one point, I have included the words "reasonable and prudent," on the assumption that the Commission would not be proposing to offer KI to states and localities, and the Government would not be stockpiling KI now, if stockpiling of KI were not regarded as a reasonable and prudent measure. I highlight this only because I do not want to give anyone the excuse to accuse me of trying to slip something into the notice without the Commission's being aware of it.

Finally, I have also suggested some additions to, and one deletion from, the list of references.

Please note that this submission is, as in the past, submitted in my capacity as a member of the public, not in my official capacity as Counsel for Special Projects in the NRC's Office of the General Counsel. It was written on my own time, at home, using my own computer and materials, and relying on information available to the public in the NRC's Public Document Room.

Sincerely,



Peter G. Crane

Attachments: Draft rule change with Statement of Considerations
Markup of draft Federal Register notice from SECY-97-124

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Executive Director for Operations
General Counsel
Director, Federal Emergency Management Agency

PROPOSED RULE CHANGE

For the reasons set forth in the Statement of Considerations, the NRC is proposing to change the planning standard in 10 CFR §50.47(b)(10) by adding one sentence, as indicated by underlining:

(10) A range of protective actions have been developed for the plume exposure EPZ for emergency workers and the public. In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.